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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,424	07/23/2003	Tiecheng A. Qiao	85504D-W	9183

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EXAMINER	
HYUN, PAUL SANG HWA	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,424	QIAO ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/17/03, 4/11/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to an array of microspheres with latent colorants, classified in class 436, subclass 518.

II. Claims 18 and 19, drawn to a method of identifying biological analytes by reacting microspheres with latent colorants and tagged analytes, classified in class 436, subclass 56.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the microspheres recited in Group I can be reacted with analytes that do not have emission tags, and thus the use of the microspheres does not require the step of recording signals from the optical emission tags. Microspheres comprising dyes that can be developed only in the presence of the analyte of interest are well known in the art. Therefore, microspheres recited in Group I would be capable of detecting analytes that do not comprise emission tags.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Lynne Blank on 12/7/05 a provisional election was made with the preservation of right to traverse to prosecute the invention of Group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities:

The Specification fails to identify the commonly assigned copending applications to which this pending application relates.

Appropriate correction is required.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 fails to further limit claim 1 because the microspheres recited in claim 1 can't be arranged in a way other than a random or orderly distribution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is dependent on claim 3. Claim 8 recites that the optical signature can be used to identify a target analyte. However, claim 3 recites that the optical signature can be used to identify the microsphere. It is not clear whether the optical signature can be used to identify the microsphere, the target analyte or both. The Specification does not appear to support the use of an optical signature that is capable of identifying both the microsphere and the target analyte. However, for the purpose of examination, the claim will be interpreted to mean that the optical signature can be used to identify both the microsphere and the target analyte.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-12, 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee et al. (US 6,429,027 B1).

Chee et al. disclose a two-dimensional array of microspheres immobilized in wells of a substrate (see Figs. 1A and 1B), wherein the concentration of the wells on the substrate is at least 10,000 per cm^2 (see claim 24). The size of the microspheres can range between 0.2 to 200 microns (see lines 33-40, col. 9). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acids [see claim 12]) that binds an analyte of interest (see claim 1). The reference further discloses that the microspheres comprise a unique optical signature capable of identifying the bioactive agent (see claim 5), wherein the optical signature can be in the form of a fluorescent dye (see lines 1-7 col. 5). The fluorescence of the dyes is a photo initiated process involving the absorption of a high energy photon and the emission of a lower energy photon.

The reference discloses another embodiment of the invention comprising microspheres with biological probes in the form of identifier binding ligands (IBL) that

bind to the decoder biding ligands (BDL) of the target analyte. The reference discloses that the IBL/DBL interaction can be an interaction involving metal ion-metal ion ligands (see lines 17-25 col. 15). The reference further discloses that the IBL is a molecule that has the ability to change its color or luminescence properties once it binds to the DBL (see lines 35-50, col. 15), thus providing a means to identify the target analyte as well as the microsphere.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Zuk et al. (US 4,256,834).

Chee et al. disclose the microarray recited in claim 7, but the reference does not disclose that the optical signature is developed by the means recited in the claim.

Zuk et al. disclose an immunoassay comprising the use of a chemiluminescer that undergoes an enzyme catalyzed redox reaction to produce a detectable signal (see 1-13 col. 20). It would have been obvious to utilize a chemiluminescer disclosed by Zuk et al. as the optical signature means for the microspheres disclosed by Chee et al. The

use of such chemiluminescers would be beneficial in assays in which the assay conditions favor chemiluminescence over fluorescence.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Wang (US 4,663,277).

Chee et al. disclose the microsarray of claim 13 except for the recital of the immobilization of the microspheres by a gelation process.

Wang discloses an immunoassay for a virus accomplished by utilizing microspheres coated with antiviral antibodies. The reference discloses that the method of the immunoassay involves immobilizing the microspheres by placing the microspheres in a gel (see lines 46-50 col. 9).

It would have been obvious to one of ordinary skill in the art to further immobilize the microspheres disclosed by Chee et al. by means of a gel as taught by Wang so that the microspheres disclosed by Chee et al. are better secured within the wells of the substrate.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Walt et al. (US 6,023,540) disclose a two-dimensional array of microspheres immobilized in wells disposed at the end of an optical fiber. The microspheres comprise biological probes in the form of functional groups, and a plurality of dyes in varying ratios that define an optical signature for each type of microsphere and analyte. The

dyes display a change in its optical signature once an analyte exclusively interacts with the functional groups disposed on the surface of the microspheres, which enables one to identify the microsphere and the analyte.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PSH
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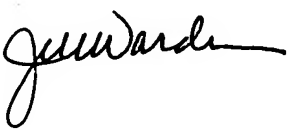

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